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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,901	04/23/2007	Darrell H. Reneker	089498.0500.US	7722

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EXAMINER	
COLELLO, ERIN L	

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
11/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,901	RENEKER ET AL.	
	Examiner	Art Unit	
	ERIN COLELLO	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed on March 10, 2010. Claims 1-5 and 16 will be prosecuted on the merits.

Applicant's arguments filed March 10, 2010 have been fully considered but they are not persuasive.

Oath/Declaration

1. Applicant's arguments, see page 4, filed March 10, 2010, with respect to the objection to the Oath/Declaration have been fully considered and are persuasive. The objection of the Oath/Declaration has been withdrawn and a new oath or declaration is not required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-5 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by **Lau et al. (US 5,876,432).**

Regarding claim 1, Lau discloses a stent comprising: a stent member (Ref 220; Column 24, Lines 55-67); a release layer, wherein the stent member is coated with the release layer (Ref 224; Column 17, Lines 58-67; Column 18, Lines 19-35; Column 23, Lines 37-47; Column 24, Lines 55-67; wherein the tubular component is a layer that is

spread over the inner surface of the stent and therefore the stent is coated with the tubular component layer); and an insoluble fibrous component, wherein the insoluble fibrous component is wrapped around the stent (Ref 222; Column 8, Lines 55-63; Column 9, Lines 34-41; Column 14, Lines 55-67; Column 15, Lines 1-31; Column 24, Lines 55-67; Column 25, Lines 1-14; wherein the fibers can be placed around the stent and therefore wrap around the stent), wherein the insoluble fibrous component forms a reinforcing thrombus plug upon degradation of the release layer (Column 15, Lines 1-61; wherein the insoluble fibrous component helps reinforce the vessel wall and isolate aneurysms and is therefore forming a thrombus plug that isolates aneurysms), and wherein the insoluble fibrous component is secured in place during implantation by the release layer (Column 24, line 55- Column 25, line 14 and 38-53; wherein the insoluble fibrous component can be imbedded within the release layer and is therefore secured in place by the release layer), the release layer being designed to degrade only after implantation of the stent is complete (Column 23, lines 30-47; wherein the release layer can be used as a temporary repair unit and can degrade under physiological conditions and wherein the release rate can be adjusted by varying the chemical structure of the release layer).

Regarding claim 3, Lau discloses that the insoluble fibrous component comprises a compound selected from poly(caprolactone), polyethylene terephthalate, fibrinogen, polyolefins, polyethylene, polypropylene, linear poly(ethylenimine), cellulose acetate, grafted cellulosics, poly (L-lactic acid), poly (ethyleneoxide), poly (hydroxyethylmethacrylate), poly (glycolic acid), poly vinylpyrrolidone, polyethylene

glycol, polyethylene oxazoline, polyester, polyacrylic acid, polyacrylic acid esters, polyphosphezines, polycyanoacrylate, polyvinyl amines, polyethylene imines, polyethylene amines, polyacrylamides, cellulose, polyorthoesters, polyanhydrides, polyketals, polyacetals, polyureas, and polycarbonate (Column 14, Lines 55-67; Column 15, Lines 1-31; Column 25, Lines 1-14).

Regarding claim 4, Lau discloses that the insoluble fibrous component comprises Dacron (Column 25, Lines 1-14; wherein Extrinsic Evidence Rhodes (5,665,117) teaches that Dacron is a thrombogenic and fibrogenic material that initiates the formation of a thrombus in order to stimulate the incorporation of the prosthesis by fibrosis to the vessel wall in order to ensure a complete and permanent seal and prevent rupture of an aneurysm (Column 7, lines 7-36)).

Regarding claim 5, Lau discloses that the thrombogenic material at least partially blocks the entrance to a structure selected from the group consisting of an aneurysm, a fistula, and an opening in a blood vessel wall (Column 15, Lines 1-61; wherein the stent helps reinforce the vessel wall and isolate aneurysms).

Regarding claim 16, Lau discloses a method for using the stent of claim 1, the method comprising the step of implanting the stent in a living organism (Figures 14A-C; Figures 15A-C; Column 26, Lines 24-49.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Lau et al. (US 5,876,432).**

Regarding claim 2, Lau discloses that the insoluble fibrous component comprises a small fiber but fails to explicitly disclose that it is a nanofiber

However, it would have been an obvious matter of design choice to make the fiber a nanofiber, since it has been held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984).

Response to Arguments

Applicant's arguments filed March 10, 2010 have been fully considered but they are not persuasive.

- Applicant argues that the devices of Lau will not permit for a time lag between implantation and release of the sealing mesh component and that the devices of Lau can suffer movement of the mesh at an inopportune time, rendering such devices useless for their intended purposes.

  The Examiner respectfully disagrees. Lau discloses all of the claimed structure including a stent (220) and an insoluble fibrous component (222) contained within a release layer (224); wherein the insoluble fibrous component can be imbedded within the release layer and is therefore secured in place by the release layer

(Column 24, line 55- Column 25, line 14 and 38-53). Additionally, Lau discloses that the release layer can be used as a temporary repair unit and can degrade under physiological conditions and that the release rate can be adjusted by varying the chemical structure of the release layer (Column 23, lines 30-47). Since Lau discloses all of the claimed structure and discloses that the release layer 224 can degrade under the physiological conditions that occur when the stent is implanted within the body and that the release rate can be adjusted as desired, the arguments are not persuasive.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN COLELLO whose telephone number is (571)270-3212. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. C./
Examiner, Art Unit 3734

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3776